



21st Century Cures Roundtable

Convened by Congressman Gus Bilirakis

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Testimony by:

Thomas Sellers, PhD, MPH

Director, Cancer Center and Moffitt Research Institute

Executive Vice President

We are grateful for this opportunity to present information on the Oncology Research Information Exchange Network (ORIEN) – a national cancer research alliance founded by Moffitt Cancer Center and the Ohio State University Comprehensive Cancer Center-Arthur G. James Cancer Hospital and Richard J. Solove Research Institute.

ORIEN is established to accelerate the development of new lifesaving therapies for cancer patients, a goal which aligns perfectly with the 21st Century Cures initiative led by Congressman Bilirakis and his colleagues on the House Energy and Commerce Committee.

The Committee has acknowledged that the staggering amount of time and money it now takes to bring a new drug to market – estimated at more than a decade and \$1 billion – is due largely to the difficulty in identifying and recruiting subjects for clinical trials. Further, it has been acknowledged that a shortage of centralized registries and the lack of coordination between institutions and with patients are also major impediments to timely evaluation of new treatments.

The ORIEN partnership seeks to overcome these obstacles by capitalizing on an already established “big data” effort that began at Moffitt that includes tissue, data, and consent to re-contact more than 100,000 patients with cancer. Ohio State has implemented the same protocol. Collectively, these two NCI-designated comprehensive cancer centers anchor a growing nationwide consortium of other centers who share our sense of urgency to advance cures for cancer.

Although there are currently websites that list available clinical trials across the country, to realize the potential of personalized medicine, the immediate need is to match the molecular profile of a tumor with a trial testing a drug that is designed to hit that target. The ORIEN database is annotated with molecular as well as clinical information, so that it can quickly identify patients whose genetic and demographic profiles are sought for a given study.

The ORIEN system presents a significant opportunity for pharmaceutical companies to modernize trial recruitment and facilitate adaptive clinical trial design. Since all the patients enrolled in ORIEN have consented to remain in the network from the point of their cancer diagnosis through their entire lifespan, they can be contacted when a new treatment tailored to their own unique needs is ready to be tested.

In addition to accelerating the clinical trials process, ORIEN creates a data and tissue repository through which researchers from multiple institutions can discover and validate biomarkers that will predict response to treatment and reveal targets for new therapies.

ORIEN will also help physicians deliver more effective cancer treatments at the point of care by using evidence and knowledge generated by the data warehouse to meet the needs of each patient. Through data analysis and sharing, ORIEN will provide physicians evidence of the best therapeutic options, including clinical trial treatments, personalized to each patient. This is expected to increase the likelihood of treatment efficacy, speeding response time, and potentially minimizing side effects while improving outcomes.

More information is available at www.oriencancer.org.